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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,814	03/30/2001	Miklos Csore	4175	6646

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THE REILLY INTELLECTUAL PROPERTY LAW FIRM, P.C.
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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,814	CSORE ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-26 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-26 and 28-31* is/are rejected.

7)☒ Claim(s) *24 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 20 April 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8, 10-26, and 28-31 are currently pending. Claims 9 and 27 have been cancelled.

Information Disclosure Statement

The Information Disclosure Statement filed 1 August 2005 has been considered. A signed copy of PTO Form 1449 is included with this Office Action. It is noted that this IDS has been filed in response to a Notice of Non-Compliance dated 11 July 2005. The complete copy of version 1.1.1.0 of the Safe Trace Manuel has now been entered in response to the Examiner's Requirement for Information sent 15 December 2004.

Claim Objections

Claims 24 and 30 are objected to because of the following informalities:

Claim 24 recites, "the presence of said directed". It appears as if there is a word missing after "directed". Perhaps Applicant intends the claim to read "the presence of said directed blood donations". Appropriate correction is required.

Claim 30 recites "antibodies presented". Perhaps Applicant intends this to read "antibodies present". Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-26, and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the following steps:

A method of managing and tracking blood products between a plurality of remote patient facilities and a central blood testing facility wherein a blood specimen is obtained from each patient who requires a blood reserve for possible transfusion and said specimen is transferred to said central blood testing facility comprising the steps:

1. providing an inventory of blood products at said central blood testing facility
2. selecting one of said blood products which has an available ***segment*** at said central blood facility
3. detaching said ***segment*** from said blood product at said central blood testing facility
4. transferring ***said one of said blood products*** from said central blood testing facility to one of said remote patient facilities
5. assigning said segment to ***said patient specimen*** for cross-matching at said central blood testing facility
6. determining ***the antigens and antibodies present in said one of said blood products*** and ***said patient specimens***
7. remote serological cross-matching each said patient specimen and said segment of said blood product at said central blood testing facility to determine their compatibility with one another ***and entering the results in said database***
8. verifying the compatibility of said one of said blood products and said patient ***specimens*** from the results entered in said database by comparing the antigens and antibodies in said one of said blood products and said ***patient specimens*** to determine whether ***each*** is present in each segment of said blood product and said ***patient specimen*** tested and storing said information in said database
9. managing said blood products by preparing a patient identification database of each of said blood products, segments, and patient specimens and storing information in said database at ***each*** of said central blood testing and remote patient facilities which ***correlates*** each of said blood products, segments and patient specimens, ***their location and movement***
10. tracking the location and movement of each of said blood products, segments and patient specimens in said database between said remote patient facilities and said central blood testing facility by displaying the information stored in said database relating to their location and movement.

In regard to step 2, the claim is vague and indefinite because it is unclear what is meant the term "segment", as italicized above. The specification states that a "segment" is a portion of a blood product that can be detached and used for testing. However, what portion of the blood is intended? It this a physical portion of a blood product, such as a vial of blood or is this a molecular component of a blood product, such as plasma? Clarification is requested.

In regard to step 4, it is unclear what "one of said blood products" is intended. Is the claim to be limited to transferring the segment from the blood products or does Applicant intend some other blood product? Clarification is requested.

In regard to step 5, it is unclear what patient specimen is intended. Is this specimen one which is different from the segment? Clarification is requested.

In regard to step 6, in which sample are the antibodies and antigens being determined? Are they determined in the segment and in the specimens? In step 5, only a singular specimen is presented, however, step 6 recites plural specimens. Are these different specimens?

In regard to step 7, there is insufficient antecedent basis in the claim for "said database". Where does the database come from? Clarification is requested.

In regard to step 8, again, there is confusion regarding the specimen/specimens. Is there to be one specimen or several specimens? Clarification is requested.

In regard to step 9, it is unclear what is being correlated. Are the blood products, segments, and specimens being correlated to their movement and location or are the blood products, segments, specimens, location, and movement being correlated to something else? Clarification is requested through clearer claim language.

In regard to claim 3, the said blood products and said specimens are unclear because of the indefiniteness of these terms in claim 1. Clarification is requested.

In regard to claim 4, there is insufficient antecedent basis in the claim for "said patient identification information". Clarification is requested.

In regard to claim 5, the term "patient bar" is indefinite. It is unclear what is meant by patient bar? Is this a bar code or is some other limitation intended? Clarification is requested.

In regard to claim 6, it is unclear which segment, blood product or specimen is intended to be limited, due to the indefiniteness of these terms in claim 1. Clarification is requested.

In regard to claim 10, the claim is vague and indefinite because it is unclear what is meant the term "segment". The specification states that a "segment" is a portion of a blood product that can be detached and used for testing. However, what portion of the blood is intended? It this a physical portion of a blood product, such as a vial of blood or is this a molecular component of a blood product, such as plasma? Clarification is requested.

In regard to claim 11, the recitation of "after entering said information into said database" is unclear. To what information is this limitation referring? What information about antigens and antibodies is entered into the database? Clarification is requested.

In regard to claim 16, there is insufficient antecedent basis in the claim for "recording prior transfusion reaction history", as there was no transfusion reaction step in claim 10. Clarification is requested.

In regard to claims 20 and 26, it is unclear in the forth means, what results of comparing antigens and antibodies are recorded. To what are the antigens and antibodies compared? Are

the patient antibodies and antigens compared to those in the blood product or to some other component for testing? Clarification is requested.

In regard to claim 22, there is insufficient antecedent basis in the claim for "the prior transfusion", as there was no transfusion in claim 20. Clarification is requested.

Claim 29 recites "segment". The claim is vague and indefinite because it is unclear what is meant the term "segment". The specification states that a "segment" is a portion of a blood product that can be detached and used for testing. However, what portion of the blood is intended? It this a physical portion of a blood product, such as a vial of blood or is this a molecular component of a blood product, such as plasma? Clarification is requested.

Claim 30 is indefinite because it is unclear what is intended by the limitation "a means for entering antigens and antibodies presented in said blood system". What about the antigens and antibodies are being entered? The name of the antigens and antibodies, certain information about the antigens and antibodies, or some other embodiment? Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Brodheim Rejection

Claims 1-8, 10-26, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Brodheim (Symposium on Computers in the Clinical Laboratory, "Automated Systems in Blood Banking", in Clinics in Laboratory Medicine (1983) Vol. 3, No. 1, pages 111-132).

The instant claims are drawn to a method and system for managing and tracking blood products.

In regard to claims 1, 10-20, 25, 26, 29, and 30 Brodheim teaches automation of blood banking procedures, including the availability of centralized information pertaining to available blood products from a donor blood bank (page 112, paragraph 1; page 117, paragraph 5). Further, blood products may be requested for transfer to remote facilities (page 120, line 1, page 125, paragraph 4). Brodheim teaches that the blood products are managed such that compatibility testing is performed between patient and donor blood products (page 113, lines 1-4). Antibodies and antigens are compared (page 124, paragraph 2; page 125, paragraphs 1 and 2). All information may be managed such that tracking the blood products is efficient from a centralized database (page 129, paragraph 3). Blood types from patients and donors are assessed in the laboratory system (page 112, paragraph 5). Expiration dates of samples are monitored (page 113, paragraph 4; page 117, paragraph 6)

In regard to claims 2, 7, 21, 22 Brodheim teaches the storing of patient information, such as patient identifying information and the quantity and types of blood components needed (page 112, paragraph 4; page 116, paragraph 6 to page 117, paragraph 1).

In regard to claim 3, Brodheim teaches tracking of blood products so that each product is linked to the donation product from which it was derived (page 126, paragraph 1).

In regard to claims 4 and 31, Brodheim teaches display of the patient identification information (page 114, paragraph 3 (retrieving information through terminals).

In regard to claim 5, Brodheim teaches retrieval of information from remote locations (page 114, paragraph 5).

In regard to claims 6, Brodheim teaches information on crossmatching of patient and donor samples stored in the database and labeled (page 117, paragraph 4).

In regard to claim 8, Brodheim teaches bar coding the samples based on compatibility sampling and other criteria (page 117, 6).

In regard to claims 23 and 24, Brodheim teaches a donation database that stores information on each blood donation for future access, meeting the limitations of claims 23 and 24 (page 116, paragraphs 3-5)

In regard to claim 28, donations reserved are taught at page 116, paragraph 5 (i.e. the database stores information on specific donations)

Safwenberg et al. Rejection

Claims 1-6, 8, 10-16, 18-22, 25, 26, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Safwenberg et al. (Vox Sanguinis (1997) Vol. 72, pages 162-168).

The instant claims are drawn to a method and system for managing and tracking blood products.

In regard to claims 1, 10-16, 18-22, 25, 26, and 28-31, Safwenberg teaches the ABCD system and procedure for delivery of blood units from a donor to a patient (see Figure 1, page 164). This involves providing an inventory of blood products from donors (page 163, column 1,

paragraph 2 and Figure 1 (blood in stock), page 164). Blood products are selected and transferred to the patient (page 163, column 2, paragraph 2). Samples are crossmatched and antibody/antigen testing is performed and verified (page 163, column 1, paragraph 2). Patient specific information is stored, which correlates to blood group information, type components, etc at page 163, column 1, paragraph 2. Tracking is maintained in the computer file and bar coding is used to monitor the blood products (page 163, column 2, paragraph 1 and 2).

In regard to claim 2, Safwenberg teaches storing patient information such as reaction histories, blood components, blood type, expiration date (page 163, column 1, paragraph 2).

In regard to claim 3, component tracking is performed (page 163, column 2, paragraph 1 and 2).

In regard to claim 4, a computer system is taught, which contains a display of information (page 163, column 1, paragraph 1; also page 167, column 1, paragraph 1 (paper print out display).

In regard to claim 5, the patient bar code is registered in the computer system, which is available on the ward (remote location) and in the central facility (bar code page 163, column 2, paragraph 1).

In regard to claim 6, the blood components are assigned to a patient and the location of the components are known (page 163, column 2, paragraph 2).

In regard to claim 8, an identification tag is generated based upon crossmatching (page 163, column 2, paragraph 2).

Prior Art Made of Record

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

1. Butch et al. (Transfusion (1994) Vol. 34, No. 2, pages 105-109).

2. Cheng (Vox Sanguinis (1998) Vol. 74 (Suppl. 2), pages 427-429).

3. Kern et al. (Clinics in Laboratory Medicine (1996) Vol. 16, No. 4, pages 947-960).

4. Jeter et al. (Journal of Hematotherapy (1994) Vol. 3, page 103-110).

5. Coovadia et al. (Transfusion Science (1997) Vol. 18, No. 4, pages 517-522).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 15, 2006
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow
Patent Examiner